

EXHIBIT 2

SUPPLEMENTAL EXPERT REPORT OF DR. MICHAELA ALMGREN

1. The attorneys who represent death-sentenced prisoner Terry Lynn King asked me to submit an expert medical and scientific opinion in this case. I offered an initial expert report on November 17, 2021. I am now further supplementing the opinions that I offered in that initial report based on my review of additional pharmacy related documents (Defts. Supp. Resp. 02.14.2022).

2. My experience, qualifications, testimony in prior cases, and fee schedule for this case are set forth in my initial report.

3. More documents, studies, and other pertinent information may become available to me at a later date, and I reserve the right to take such materials into account and to modify or supplement my opinions accordingly. I may also be present at hearings or at trial and may consider any testimony or other evidence related to my opinions and modify or supplement my opinions accordingly.

I. Inconsistent and poorly maintained compounding records lack important details and integrity.

4. The compounding log page produced by Defendants and Bates-labelled 014142, dated 11/18/2019 does not show what drug was made in the compounding process. The compound contains excipients only such as pH adjusters, a preservative, and water for injection. It is not clear what the purpose of this compound was, as there were no active pharmaceutical ingredients listed. This is concerning because although the records look consistent with the midazolam recipe, the active pharmaceutical ingredient (API) for midazolam appears to be missing. This mixture of excipients could have been used in lieu of midazolam, and it would have had no pharmacological effects due to the lack of API.

5. There are additional concerns related to the integrity of the report from 11/18/2019 as it appears that, while the compound was prepared on 11/18/2019, at the bottom of the report is a note stating that the report was last modified on 11/9/2021. Why the report was modified and what was changed is not clear; it appears the compound was prepared but then the compounding logs documenting the actual preparation were changed two years later. Additionally, the handwritten date states that the log was completed on 11/18/19. If the sheet was modified as it says, it would have been printed again, and should have been dated with 2021 date, and it should be noted what modifications were implemented. This modification without explanation reflects a risk that the compound was not in fact created as noted.

Date entered: 11/18/2019 1:59:06 PM
Checked by: [REDACTED]

Last modified: 11/9/2021 3:16:15 PM

Date: 11/18/19

II. The master recipe is not being followed at times.

6. Also concerning is the fact that the master recipe is apparently not always used by the compounding pharmacy and no explanation why there are modifications to the recipe is provided. The compounding log from 4/24/2019 produced by Defendants and Bates-labelled 014143 shows that, when midazolam was compounded on that date, only 10 millilitres of 1% hydrochloric acid (HCl) was used to adjust the pH of the solution in order for midazolam to dissolve. According to the compounding recipe listed and included in this report, however, it is necessary to add approximately 5.6 millilitres of 1% HCl for every 10 millilitres of final volume to be prepared, which means that the amount added should be around 30.8 millilitres (final volume is 55 millilitres, thus $55/10=5.5$ and therefore $5.5 \times 5.6=30.8\text{mL}$). However, only 10 millilitres of HCl was added to the solution, which is not a sufficient amount according to the recipe. This can lead to formation of precipitant over time, with midazolam crystalizing and

falling out of solution. When adding up to the final total volume, the final preparation according to the compounding log contains 52.3 millilitres of the excipients. The volume that was supposed to be supplied by the 1% HCl was substituted with water for injection to dilute to volume. This demonstrates that the master recipe is not being followed, and there is greater potential for the compound to fall out of solution due to the insufficient quantity of HCl.

7. The compounding log for 7/20/2018 produced by Defendants and Bates-labelled 014144 shows that the same amount of the final volume of midazolam was prepared as on 4/24/2019 (55 mL), however, this time the correct amount of HCl (30.8mL) was utilized. It is also interesting to note that the final volume of total excipients is 49.9 millilitres. Considering that the same formula recipe with the same final volume is being used, it is questionable why are there such differences in final volume between those two compounds. This demonstrates an unusual and concerning lack of precision in compounding of the drugs. This also raises the possibility that the drugs could be inaccurately compounded in additional ways that are not explicitly reflected in these records. According to USP Chapter 797 “Compounding personnel are responsible for ensuring that compounded sterile products are accurately identified, measured, diluted, and mixed and are correctly purified, sterilized, packaged, sealed, labelled, stored, dispensed, and distributed.” It appears that this guidance from the USP Compendium is not being followed.

III. A “Laboratory Report” (included with the compounding log information) for midazolam injection that was tested on 7/21/2020 does not provide sufficient information about the drug quality and purity.

8. Since the quality of the midazolam API is questionable as it does not meet USP grade requirements (listed as BP grade in the inventory section of the materials provided for review)

and there are no quality reports submitted to show otherwise, it is imperative to test the compounded drug for the presence of impurities, as required by USP Monograph for midazolam injection. There is no indication that the laboratory did so. Because the presence of impurities can lead to unwanted and unpredictable reactions, as impurities could be pharmacologically active, this failure means that the drug may not work as intended.



Michaela Almgren, PharmD, MS

April 12th, 2022